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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,520	10/31/2005	Hans Loibner	4518-0108PUS1	3426

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EXAMINER	
DUFFY, BRADLEY	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	04/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 04/11/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/524,520	LOIBNER ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed August 18, 2005, has been entered. Claims 1-15 have been amended. Claims 17-24 have been added.

2. Claims 1-24 are pending in this application and are currently subject to restriction.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 17, insofar as the claim is drawn to a method for the intra-operative treatment of a tumor to inhibit dissemination of tumor cells comprising administering an antibody specific for EpCAM during surgery, whereby immunocomplexing of tumor cells during the surgical intervention inhibits dissemination of tumor cells.

Group II, claim 17, insofar as the claim is drawn to a method for the intra-operative treatment of a tumor to inhibit dissemination of tumor cells comprising administering an antibody specific for NCAM during surgery, whereby immunocomplexing of tumor cells during the surgical intervention inhibits dissemination of tumor cells.

Group III, claim 17, insofar as the claim is drawn to a method for the intra-operative treatment of a tumor to inhibit dissemination of tumor cells comprising administering an antibody specific for CEA during surgery, whereby

immunocomplexing of tumor cells during of the surgical intervention inhibits dissemination of tumor cells.

Group IV, claim 17, insofar as the claim is drawn to a method for the intra-operative treatment of a tumor to inhibit dissemination of tumor cells comprising administering an antibody specific for LEWS Y during surgery, whereby immunocomplexing of tumor cells during the surgical intervention inhibits dissemination of tumor cells.

Group V, claim 17, insofar as the claim is drawn to a method for the intra-operative treatment of a tumor to inhibit dissemination of tumor cells comprising administering an antibody specific for Sialyl-TN during surgery, whereby immunocomplexing of tumor cells during the surgical intervention inhibits dissemination of tumor cells.

Group VI, claim 17, insofar as the claim is drawn to a method for the intra-operative treatment of a tumor to inhibit dissemination of tumor cells comprising administering an antibody specific for Globo H during surgery, whereby immunocomplexing of tumor cells during the surgical intervention inhibits dissemination of tumor cells.

Group VII, claim 17, insofar as the claim is drawn to a method for the intra-operative treatment of a tumor to inhibit dissemination of tumor cells comprising administering an antibody specific for GD2 during surgery, whereby immunocomplexing of tumor cells during the surgical intervention inhibits dissemination of tumor cells.

Group VIII, claims 1-15, and 17-24, insofar as the claims are drawn to a method for the intra-operative treatment of a tumor to inhibit dissemination of tumor cells comprising administering an antibody specific for GD3 during surgery, whereby

immunocomplexing of tumor cells during the surgical intervention inhibits dissemination of tumor cells.

Group IX, claim 17, insofar as the claim is drawn to a method for the intra-operative treatment of a tumor to inhibit dissemination of tumor cells comprising administering an antibody specific for GM2 during surgery, whereby immunocomplexing of tumor cells during the surgical intervention inhibits dissemination of tumor cells.

Group X, claim 16, drawn to a kit for the intra-operative treatment of tumor patients, comprising
a) a medicament based on an antibody directed against a tumor-associated antigen, and
b) a means for the diagnostic determination of malignant tumor cells which are immunocomplexed with the antibody.

Group XI, claims 11 and 23-24, insofar as the claims are drawn to a method for the treatment of a tumor to inhibit dissemination of tumor cells comprising administering an antibody directed against a tumor-associated antigen before surgery, whereby immunocomplexing of tumor cells during the surgical intervention inhibits dissemination of tumor cells.

4. Claims 1-16 and 18-22 are linking claims, linking the inventions of Groups I-IX. Notably, since claim 11 is directed to administering the antibody during the surgical intervention, i.e. intraoperatively, or, in the alternative, administering the antibody before the surgical invention which are directed to inventions that are deemed to have different special technical features, if any of groups I-IX are elected, claim 11 will only be examined to the extent that it reads on administering the antibody during surgery, while if Group XI is elected claim 11 will be examined to the extent it reads on administering the antibody before surgery. The restriction requirement among the linked inventions is

subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature[1]. The technical feature recited in claim 1 appears to be the inhibition of dissemination of tumor cells by a process comprising administering an antibody directed against a tumor-associated antigen during surgery. The claim lacks inventive step over of Weitz et al (Seminars in Surgical Oncology, 20:329-333, 2001) in view of Nakashio et al. (Int. J. Cancer:70:612-618,1997). Weitz et al teach a method of administering antibodies during surgery to prevent tumor dissemination (see entire document, e.g., abstract and page 333). Weitz et al do not teach that the antibodies administered are directed against tumor-associated antigens. Nakashio et al teach a method for inhibiting the dissemination of tumor cells comprising administering antibodies directed against the tumor-associated antigens, CD44H and β1

[1] M.P.E.P. §1893.03(d) states: "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art."

integrin (see whole document, e.g. page 615, right column, page 616, left column and Figure 7)). Therefore, claim 1 lacks inventive step, because it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer antibodies directed against tumor-associated antigens, such as CD44H and β1 integrin, during surgery to inhibit dissemination of tumor cells that express said antigens. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

For these reasons, the special technical feature of the invention of Group I is the inhibition of dissemination of tumor cells by a process comprising administering an antibody specific for EpCAM during surgery.

The special technical feature of the invention of Group II is the inhibition of dissemination of tumor cells by a process comprising administering an antibody specific for NCAM during surgery.

The special technical feature of the invention of Group III is the inhibition of dissemination of tumor cells by a process comprising administering an antibody specific for CEA during surgery.

The special technical feature of the invention of Group IV is the inhibition of dissemination of tumor cells by a process comprising administering an antibody specific for LEWS Y during surgery.

The special technical feature of the invention of Group V is the inhibition of dissemination of tumor cells by a process comprising administering an antibody specific for Sialyl-TN during surgery.

The special technical feature of the invention of Group VI is the inhibition of dissemination of tumor cells by a process comprising administering an antibody specific for Globo H during surgery.

The special technical feature of the invention of Group VII is the inhibition of dissemination of tumor cells by a process comprising administering an antibody specific for GD2 during surgery.

The special technical feature of the invention of Group VIII is the inhibition of dissemination of tumor cells by a process comprising administering an antibody specific for GD3 during surgery.

The special technical feature of the invention of Group IX is the inhibition of dissemination of tumor cells by a process comprising administering an antibody specific for GM2 during surgery.

The special technical feature of the invention of Group X is making a kit comprising a medicament and a means for the diagnostic determination of malignant tumor cells.

The special technical feature of the invention of Group XI is the inhibition of dissemination of tumor cells by a process comprising administering an antibody specific for a tumor-associated antigen before surgery.

Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

bd
March 31, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER